K014152

510(k) Summary for the NxStage Cartridge *Express*

DEC 11 2002

Submitter's Name and Address:	NxStage Medical Inc. 439 Union Street Lawrence, MA 01483
Phone Number:	978-687-4700
Telefax Number:	978-687-4800
Contact Person:	Karen St. Onge, Director Quality Assurance and Regulatory Affairs
Date Summary Prepared:	December 17, 2001
Device Trade Name:	NxStage Cartridge *Express*
Common name:	Extracorporeal Blood Circuit w/ Hemofilter
Classification Name:	High Permeability Hemodialysis System (21 CFR 876.5860)
Substantial Equivalence:	The proposed device is substantially equivalent to other legally marketed hemofilters/hemodialyzers previously cleared by the FDA via the 510(k) Notification process such as the SYNTRA Dialyzer (Baxter Healthcare Corporation, K002210), Cobe Arylane Hemodialyzer (Gambro Healthcare, K982414), Renoflo® II Hemofilter (Minntech Corp, K923312) and to the Prisma CFM System hemofilter (Hospal Renal Intensive Care, K942679) also provided preconnected to the hemofiltration system disposable tubing set.
Device Description:	The NxStage Cartridge *Express* is an extracorporeal blood tubing set with preconnected high flux (permeability) hollow-fiber filter.
Intended Use:	For treatment of renal failure or fluid overload using hemofiltration and/or ultrafiltration.
Technological Characteristics:	The proposed device has the same technological characteristics and is similar in design and configuration compared with the predicate devices.

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Summary of Non-clinical Test:	In vitro testing was conducted to characterize performance of the NxStage Hemofilter to provide a basis of comparison to the predicate devices. Results of in vitro studies have documented that the NxStage Cartridge *Express* is substantially equivalent to the predicate devices and is suitable for the intended use specified.
Clinical Data:	Not applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2002

Ms. Norma LeMay
Senior Regulatory Affairs Specialist
NxStage Medical, Inc.
439 South Union Street
5th Floor
LAWRENCE MA 01843

Re: K014152
Trade/Device Name: NxStage Cartridge *Express*
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: September 11, 2002
Received: September 12, 2002

Dear Ms. LeMay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K014152

Device Name: NxStage Cartridge *Express*

Indications for Use: The NxStage Therapy System is indicated for treatment of renal failure or fluid overload using hemofiltration and/or ultrafiltration. The NxStage Cartridge *Express* is part of the NxStage Therapy System and is intended for use with the NxStage Cycler.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguran

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014152

Prescription Use ✓ **OR** **Over-The-Counter Use**_____
(Per 21 CFR 801.109)